REMARKS

The Examiner has rejected all pending claims 1, 4-16, and 41-53 on the basis of obviousness over U.S. Patent No. 4,640,298 to Pless et al. ("Pless").

Prosecution History

The pending independent claims 1, 41, and 45 have been rejected over the prior art twice before. In the Office Action dated November 2, 2005, claim 1 was rejected as anticipated by Metzger (US 5,117,828) and claims 41 and 45 were rejected as anticipated by Chen et al. (US 5,690,691). In the Response, claim 1 was amended to clarify that the expandable electrode is longitudinally arranged, claim 41 was amended to clarify that the electrode is on inflatable means, and claim 45 was amended to clarify that the device of that claim includes a nasogastric tube which allows contact with the esophageal wall. The Examiner accepted these amendments and arguments but offered new art based rejections.

In the Office Action dated September 6, 2006, claims 1 and 45 were rejected as anticipated by Webster (US 6,292,695) and claims 1 and 41 were rejected as anticipated by Scarberry (US 4,351,330). Claim 45 was also rejected as anticipated by Tu et al. (US 6,123,718). In the Response dated December 6, 2006 all the independent claims 1, 41, and 45 were amended to clarify that the catheter device (or nasogastric tube electrode) applies an electric pulse "in order to achieve controlled intermittent asystole." Applicant argued that Webster teaches only a method of "controlling cardiac fibrillation, tachycardia, or cardiac arrhythmia" (Response of December 6, 2006, page 11) and that Scarberry teaches only to "defibrillate a patient during an emergency" (Response of December 6, 2006, page 12). The amendments and arguments were successful and in the Office Action dated February 23, 2007, all of the pending claims were allowed. This conclusion was repeated in the Office Action dated August 31, 2007. Subsequent to that (Office Action dated January 23, 2008), the Examiner rejected all of the previously allowed claims for double patenting over U.S. Patent No. 7,072,720 to Puskas. The Applicant filed a terminal disclaimer over that patent which has been accepted.

Now, in the latest Office Action, the Examiner has again raised a prior art rejection of the previously allowed claims and has cited a reference that was provided to the Examiner in the IDS submitted February 28, 2005- prior to the first Office Action. The newly cited patent, Pless, fails

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to render the claimed invention obvious for reasons similar to the previously cited patents Webster and Scarberry.

Pless

Pless teaches an electrode probe for stimulation of the heart from the interior of the esophagus. The stimulation is used for "patients with sudden instance of heart failure" (col. 1, ll. 22-24) to provide emergency pacing such as in cases of heart arrest (asystole) (col. 1, ll. 27- 29). The Pless device has two stimulation regions; one for the left atrium and one for the left ventricle (see claim 1 and FIGS. 1, 2, and 6). The focus of Pless is stated in col. 4, ll. 17-23:

> The invention is based on the surprising finding that while the distance from the wing of the nose to the heart, as measured through the esophagus, varies, as stated, from individual to individual, the distance from the transition between stomach and esophagus to the transition between left atrium and left ventricle is for practical purposes independent of the height of adults.

Pless differs from the presently claimed invention in several ways. Pless is designed to stimulate the heart, from placement inside the esophagus. Figure 6 especially illustrates this. The claimed invention, on the other hand, is for stimulation of the vagus nerve. Pless nowhere mentions stimulation of the vagus nerve.

Pless teaches using the device for the opposite reason of the claimed invention. Pless teaches using the device to apply electric current on a heart already in asystole (non-beating) or with an arrhythmic, irregular beat to guide the heart to regular beating. The Pless device is essentially a rapidly deployable pacemaker.

Conversely, the claimed invention's aim is to take a heart that is already beating in a normal fashion and stop it in a controlled way ("applying an electric pulse to the expandable electrode in order to achieve controlled intermittent asystole"). Controlled intermittent asystole (or CIA, using the acronym developed by the Applicant) is described in the present specification on page 2 of the specification. CIA is a way to "provide brief intervals of cardiac quiescence" so that cardiac motion can be minimized and procedures, such as bypass graft, can be performed more safely and accurately. The specification describes in detail how the claimed device can be used to achieve CIA.

The Examiner's argument is thus that Pless, which teaches application of a current to start the heart, teaches the claimed invention of a method to temporarily stop or slow the heart.

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Serial No. 09/980,421
Puskas
Response to Office Action

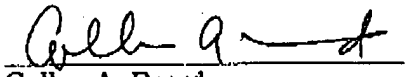
The Examiner states that one skilled in the art would "have found it obvious to use the device to control intermittent asystole because Pless et al teach in case of asystole where the heart emits no EKG recordable impulses, stimulation signals will be applied by all the electrodes until the heart begins beating again and EKG signals can be recorded."

Applicant agrees that Pless teaches that in the case of asystole, the device can be used to start the heart beating again. But Pless does not teach or suggest that a state of CIA is desirable or can be achieved. Pless is concerned with getting the heart beating – not with getting the heart to temporarily stop or slow beating.

The claimed device is not to "control intermittent asystole" but rather to achieve "controlled intermittent asystole". The claimed device can be applied to a normal beating heart (via the vagus nerve) to achieve controlled intermittent asystole. Pless on the other hand teaches a device applied to a non-beating or irregularly beating heart. Pless does not teach how to achieve controlled intermittent asystole, but rather teaches achieving a regular heart beat.

Accordingly, Pless does not teach or render obvious the claimed invention and prompt allowance of the claims is warranted and appreciated.

Respectfully submitted,



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